Docket 226/242

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Cheng et al.

Serial No.: 08/900,559

Filed: 07/25/97

For: METHOD OF USE OF ONE STEP IMMUNOCHROMATOGRAPHIC DEVICE FOR STREPTOCOCCUS A ANTIGEN

Group Art Unit: 1641

Examiner: Carol A. Spiegel

May 10, 1999

PRELIMINARY REMARKS

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Applicants believe that no fee is due for the filing of these Preliminary Remarks. If any fee is due, please charge any necessary fees to account 12-2475.

Applicants previously submitted the Declaration of Richard A. Schwartz during the prosecution of Application Ser. No. 08/900,559. In the Advisory Action mailed December 28, 1998, the Examiner indicated that that the Declaration of Richard A.

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(37 C.F.R. §1.10)

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Schwartz was insufficient to overcome rejections based on Imrich et al. (US 5,415,994) alone or in combination with Bogart et al. (US 5,494,801) and Murray (US 3,957,436) as set forth in the last Office action because it did not make reference to specific claims of the subject application, no specifics were provided for the conditions of comparative testing with Quidel Quick Vue™ In-Line Strep A Test. and it was unclear whether the Quick Vue™ was identical with Imrich et al. or not.

Submitted with these preliminary remarks is a Declaration of Richard A. Schwartz signed February 26, 1999, containing information previously set forth in the earlier submitted declaration and additional information noted by the Examiner. Paragraph 3 of the February 26, 1999 Declaration of Richard A. Schwartz states that the method used with the OSOM™ device exemplifies claim 10 of the subject application. Paragraph 8 indicates that the OSOM™ and QuickVue™ tests were performed according to the manufacturers inserts, and provides information regarding the conditions for the assays. Paragraph 5 states that the QuickVue™ device exemplifies the device to which claim 1 of Imrich et al., US Patent No. 5,415,994 is drawn.

With the addition of the information cited above, and for the reasons discussed in the Amendment and Remarks of December 1, 1998 submitted for the Examiner's consideration with respect to Application Ser. No. 08/900,559 (which Applicants requested be entered upon filing of this continuation application), Applicants believe that the Declaration of Richard A. Schwartz is now sufficient to overcome the rejections based on Imrich et al.

Applicants have set forth remarks below which are substantially similar to Applicants' remarks regarding the rejection under 35 U.S.C. § 103 based on Imrich et

al., which now refers to the paragraph numbering found in the February 26, 1999 Declaration of Richard A. Schwartz.

35 U.S.C. § 103

Applicants respectfully assert that none of the claims are made obvious by Imrich et al.

Although the Federal Circuit noted in Interconnect Planning Corp. v. Feil, 227 U.S.P.Q. (BNA) 543 (Fed. Cir. 1985) that the claimed invention and references must each be evaluated as a whole, the Federal Circuit concluded that the district court had improperly reconstructed the claimed invention from separate components in the prior art:

> "From its discussion of the prior art it appears to us that the court, guided by the defendants, treated each reference as teaching one or more of the specific components for use in the Feil system, although the Feil system did not then exist. Thus the court reconstructed the Feil system, using the blueprint of the Feil claims. As is well established, this is legal error. Id. at 548.

Moreover, the Federal Circuit further noted that "[t]here must be 'something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination'." Id. at 551 (quoting Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick Co., 730 F2d 1452, 1462, 221 USPQ 481, 488 (Fed. Cir. 1984)).

The test that the prior art must be viewed as a whole avoids improper focus on the obviousness of substitutions and differences between the claimed invention and the prior art. Gillette Co. v. S.C. Johnson & Son, 919 F.2d 720, 16 U.S.P.Q.2d (BNA) (Fed. Cir. 1990). Thus, there must be some reason for combining elements other than hindsight reconstruction. Interconnect Planning Corp. at 551.

Moreover, an invention is not unpatentable because it was "obvious to try." In re O'Farrell, 853 F.2d 894, 902, 7 U.S.P.Q. (BNA) 337 (Fed. Cir. 1988).

Here, as discussed above, Imrich describes only the use of devices containing both the immunoassay test strip and an extraction chamber in fluid communication with the test strip. Imrich does not explicitly describe or suggest a method for detecting a Strep A antigen where the assay chamber is separated from the immunoassay device.

In the instant device, however, spatial separation of the assay chamber from lateral flow contact with the sample receiving region of the lateral flow immunochromatographic assay test strip permits greater control over the length and efficiency of extraction, and the sensitivity of the assay. For example, as noted at page 63 of the specification, a device within the scope of the claimed invention is able to detect Streptococcus cells when present at a concentration as low as 4×10^5 per swab, while the one-step Quidel device can detect Streptococcus cells only when present at a concentration of 8×10^5 cells/swab. In addition, in a study comparing the sensitivity of the OSOM™ Strep A test with the sensitivity of the Quidel QuickVue™ Strep A test, Dr. Richard H. Schwartz determined that the OSOM™ Strep A test had an overall sensitivity of 95%, while the QuickVue™ Strep A test had an overall sensitivity of 87%. February 26, 1999 Declaration of Richard A. Schwartz at ¶ 7; Schwartz, Richard H., Pediatric Infectious Disease J., 16(11):1099-1100 (November 1997), Exhibit 2 to the February 26, 1999 Declaration of Richard A. Schwartz.

The OSOM™ Strep A immunodiagnostic test strips are not contained in a bulky plastic or cardboard housing, and are therefore compact enough to be directly inserted into a sample chamber small enough to permit efficient sample extraction. (February

26, 1999 Declaration of Richard A. Schwartz at ¶ 4). Also, because the time from the start of the sample extraction to initiation of the lateral flow immunoassay can be controlled by controlling the time at which the device is inserted into the sample chamber, there is greater control over mixing of the sample with the reagents, and the length and efficiency of extraction. (February 26, 1999 Declaration of Richard A. Schwartz at ¶ 4). This results in greater sensitivity of the assay, compared to assays in which sample mixing, and the length and efficiency of extraction cannot be controlled. (February 26, 1999 Declaration of Richard A. Schwartz at ¶ 4).

In contrast to the OSOM™ Strep A test strip, the QuickVue™ device contains a bulky housing for the immunodiagnostic test strip. (February 26, 1999 Declaration of Richard A. Schwartz at ¶ 5). This housing contains a sample extraction chamber in flow communication with the test strip. (February 26, 1999 Declaration of Richard A. Schwartz at ¶ 5). In this device, flow from the sample extraction chamber onto the test strip begins almost as soon as the extraction reagents are added to the sample in the sample chamber. (February 26, 1999 Declaration of Richard A. Schwartz at at ¶ 6). In Strep A tests using these devices, samples cannot be mixed as vigorously with reagents as in a separate sample chamber, and there is less time for extraction prior to initiation of the assay. (February 26, 1999 Declaration of Richard A. Schwartz at ¶ 6). This results in a lower sensitivity of the immunodiagnostic test. (February 26, 1999 Declaration of Richard A. Schwartz at ¶¶ 6).

Moreover, other immunoassays in use prior to these one-step assays required further manipulation of the sample, such as pipetting or pouring, following extraction of the sample. (February 26, 1999 Declaration of Richard A. Schwartz at ¶ 9). This

introduced additional sources of error into the test and required performance of the test by more qualified personnel. (February 26, 1999 Declaration of Richard A. Schwartz at ¶ 9).

In addition, because the prior art describes one-step methods using devices with unwieldy plastic housings unlikely to fit within a sample chamber small enough to obtain efficient extraction, it is not obvious to insert the immunoassay device into the sample chamber to initiate the assay. February 26, 1999 Declaration of Richard A. Schwartz at ¶ 10.

Moreover, taken together, Imrich, Bogart, and Murray (US 3,957,436) do not teach a method for determining the presence or absence of a Streptococcus antigen, where separate immunoassay devices and an extraction chamber are provided, where the extraction solution comprises 0.2-5M sodium nitrite and 0.02-2M acetic acid, or where the solution contains a color indicator to indicate proper preparation. As discussed above, Imrich fails to teach or suggest a method for the detection of an analyte where the immunoassay test strip is not in flow communication with the extraction chamber. In addition, as noted at page 10 of the Office action mailed 9/2/98, Imrich does not teach vigorous mixing of the swab and extraction reagents for at least 10 seconds, or an extraction solution where the addition of 0.3 M acetic acid to a color-indicator spiked 2 M sodium nitrite solution changes the color of the final extraction solution.

Applicants therefore respectfully assert that the claimed invention is not obvious in light of Imrich et al., either alone or in combination with Bogart and/or Murray.

CONCLUSION

For the reasons set forth above, Applicants believe that claims 10-20 clearly state that the claimed invention is directed to a method for detecting a Streptococcus antigen where an immunoassay device, and a separate assay chamber are provided. The claims also clearly state that the immunoassay device is inserted into the assay chamber after completion of extraction of the sample. Moreover, Applicants respectfully assert that the claims are not anticipated nor made obvious by Imrich et al., which describes only methods using devices in which the immunoassay test strip is in flow communication with the extraction chamber. Applicants thus believe that the claims are in condition for allowance.

Respectfully submitted,

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Dated: May 10, 1999

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